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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,808	12/13/1999	AVI J. ASHKENAZI	P0978-1C1	1650

7590 02/04/2005  
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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/459,808

Applicant(s)

ASHKENAZI, AVI J.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 69-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 80-87 is/are allowed.
- 6) ☒ Claim(s) 69-73, 75, 77 and 78 is/are rejected.
- 7) ☒ Claim(s) 74, 76 and 79 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

Claims 69-87 are pending and being examined to the extent that they read upon the elected species 5-FU and polyethylene glycol.

5

***Claim Rejections - 35 USC § 103***

Claims 69, 77, 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiley (25, cited by Applicants).

Applicants argue that the examiner admits that Wiley does not teach the use of TRAIL polypeptides. Applicant's arguments have been fully considered but they are not  
10 persuasive. Wiley is silent with respect to the treatment of blastoma only in the sense that Wiley does not anticipate the treatment of blastoma.

Applicants argue that Wiley's disclosure would not motivate one of ordinary skill in the art to treat blastoma or to reasonably believe that the results with leukemia, lymphoma, and melanoma would similarly apply to blastoma cells. Applicants argue that  
15 although Wiley may provide an obvious to try approach to the treatment of blastoma, there would be no reasonable expectation of success. Applicant's arguments have been fully considered but they are not persuasive. The "blastoma" of the claims encompasses blastomas of any and/or all tissues. Lymphoma is a general term for various neoplastic diseases of the lymphoid tissue. Leukemia is a malignant disease of the blood-forming  
20 organs. Wiley's teachings to treat cancer, leukemia, and lymphoma would have suggested and would have given direction to those of ordinary skill in the art that they should treat blastomas of cancer, lymphoid tissue, or blood forming organs because the "blastoma" of the claims encompasses blastomas of any and/or all tissues, including

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lymphoid tissue or blood-forming organs. In the absence of secondary considerations, the differences between Wiley and the claimed invention as a whole would have been obvious. Obviousness does not require absolute predictability, only a reasonable expectation of success, i.e., a reasonable expectation of obtaining similar properties. The sensitivity of many cancer cell lines to TRAIL mediated killing (Example 9, referred to at column 18, full paragraph 1) provides a reasonable expectation of success in treating blastomas. Applicants' argument that there would be no reasonable expectation is unsupported.

10           Claims 69, 70-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiley (25, cited by Applicants) as applied to claim 69 above, and further in view of Gmeiner (A).

          Applicants argue that Wiley does not teach the treatment of blastoma. These arguments have been fully considered, but they are not persuasive for the reasons  
15   discussed above.

          Claims 69, 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiley (25, cited by Applicants) as applied to claim 69 above, and further in view of Davis (e15).

20           Applicants argue that Wiley does not teach the treatment of blastoma. These arguments have been fully considered, but they are not persuasive for the reasons discussed above.

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***Conclusion***

Claims 80-87 are allowable. Claims 74, 76, and 79 are objected to.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any  
10 extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

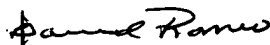
15 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300

20 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

DSR  
FEBRUARY 1, 2005